



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,552	10/07/2005	Marc De Block	58764.000049	2007
21967 7590 06/12/2007 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER KUMAR, VINOD	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/552,552

Applicant(s)

DE BLOCK, MARC

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/30/2005; 10/07/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group V, claims 9-16 and SEQ ID NO: 3 in the paper filed on April 5, 2007 is acknowledged.

Applicants argue that the special technical feature of the invention is a DNA comprising a nucleotide sequence encoding a ParG inhibitory molecule and an operably linked plant expressible promoter such that the DNA can be used in the claimed methods to produce plants tolerant to stress conditions. Applicants further argue that that US Patent No. 6,395,543 ('543) does not teach this special technical feature, and thus there is no lack of unity and Groups I-VII should be examined together. Applicants further argue that Groups I-V be rejoined because the restricted groups share the same technical feature (response, page 8, lines 1-18).

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that the technical feature linking Groups I-VII is a nucleotide sequence encoding ParG inhibitory RNA molecule, and '543 patent clearly discloses an antisense or double stranded nucleic acid molecules inhibiting ParG gene expression in plant cells using a DNA construct or vector which comprises a plant-specific promoter operably linked to said molecule. It is therefore, maintained that the technical feature linking the inventions of Groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

It is further maintained that different nucleotide sequences and amino acid sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute different inventive concepts. Furthermore, it must be noted that since 1996, databases and resources allocation at the PTO have changed and the examination of additional sequences on the merits in the instant application would present a burden on PTO resources.

Accordingly, Claims 1-8, and SEQ ID NOs: 2, 4, 15, 16, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 5, 2007. Claims 9-16, and newly added claims 20-21 in conjunction with the elected SEQ ID NOs: 1 and 3 are examined on merits in this Office action. This restriction is made FINAL.

This application contains claims 1-8, and SEQ ID NOs: 2, 4, 15, 16, and 23 drawn to inventions nonelected with traverse in the reply filed on April 5, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

2. Initialed and dated copies of Applicant's IDS form 1449 filed on 11/30/2005 and 10/7/2005 are attached to the instant Office action.

***Priority***

3. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Application No. EPO 03076044.1, filed 04/09/2003 has been received.

***Specification***

The disclosure is objected to because of the following informalities:

4. Page 5, lines 5, 33, insert --No.-- after "ID" and before "3".
5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. For example, page 10, lines 24, 26, 28, 30, 32, and page 11, lines 2, 4 and 5 disclose sequences which must be referred to by their sequence identifiers as required by 37 CFR 1.821.

Any sequence that appears in the specification must be identified by its SEQ ID Number and further listed in sequence listing. If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter

submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification. Failure to correct the deficiency will be held a non-responsive to this Office action.

Appropriate action/corrections are required.

### ***Claim Objections***

6. Claims 9-13, 14-15, and 16 are objected to because of the following informalities:

In claim 9, it is suggested to insert full-form of the term "ParG".

Claims 10 and 16 are objected for containing non-elected SEQ ID NOs. 2, 4, 15, 16 and 23.

In claim 13, insert "an" before another plant in line 2.

In claim 13, insert --of same species-- at the end of the claim.

In claim 14, replace "Seeds" with --A seed--.

In claim 14, insert --, wherein said seed and propagating material comprises the DNA molecule-- at the end of claim.

In claim 14, replace "a" after "of" and before "plant" with --the--.

In claim 15, replace "Plants" with --A plant--.

Claim 15 is objected for depending from a non-elected claim 8.

Appropriate action/corrections are required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 9-15 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 9-10, and 20 read on a naturally occurring DNA molecule comprising a naturally occurring plant-expressible promoter operably linked to a DNA region encoding ParG RNA molecule, and 3' end region involved in transcription termination and polyadenylation which is found in nature and thus, is unpatentable to Applicants. The DNA region of claims 9-10 and 20 can naturally undergo aberrant transcription to yield ParG inhibitory RNA molecule. The DNA molecule of claims 9-10 and 20, plant cell of claim 11, plant of claims 12 or 15, seeds of claim 14 have same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. Furthermore, the method of claim 13 can be naturally practiced through naturally occurring hybridization between a plant that naturally comprises the DNA molecule of claims 9-10 or 20, and the plant lacking said DNA molecule. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claim 9 be amended by replacing "A" in line 1 of claim 9 with "An isolated" so that it reads on a product that is not found in nature.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12-13, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "essentially of the plant cells of claim 11", which is confusing, since metes and bounds of the recitation is unclear and not defined. The specification does not provide guidelines and examples that can be considered sufficient to enable a person of ordinary skill in the art to draw a line between a sequence that is less than 100% identical to the plant cells of claim 11 and plant cells that is 100% identical to the plant cells of claim 11. See MPEP 2173.05(b).

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claim 13 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 13 is missing the essential step of expressing the DNA molecule to produce ParG inhibitory RNA molecule. The last step only comprises crossing a plant with another plant. Furthermore, the preamble recites a process for producing stress tolerant plants, whereas last recited method step is crossing a plant with another plant. But according to preamble last method step has to be producing stress tolerant plant.



Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "obtainable", which is confusing since it is not clear how else can plants be obtained?

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claim 16 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 16 is missing the essential step of expressing the DNA molecule to produce ParG inhibitory RNA molecule.

Appropriate action/corrections are required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 9-16, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA molecule comprising a plant expressible promoter operably linked to a ParG coding region of SEQ ID NO: 3 in sense and/or antisense orientation which is further operably linked to a 3' end region of a plant gene involved in transcription termination and polyadenylation, and a high light stress tolerant *Arabidopsis* or *Brassica* transgenic plant or a method of producing said transgenic plant comprising said DNA molecule, does not reasonably provide enablement for a) a DNA molecule comprising any DNA region which when transcribed yields a ParG inhibitory molecule, b) tolerance to any stress condition, and c) any

transgenic plant species expressing ParG inhibitory RNA molecule derived from SEQ ID NO: 3. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a DNA molecule comprising a plant-expressible promoter, a DNA region, which when transcribed yield a ParG inhibitory RNA molecule, and a 3' end region involved in transcription termination and polyadenylation, a plant cell, plant, seed or a method of producing a stress tolerant plant comprising said DNA molecule, or wherein said DNA region comprises a nucleotide sequence in sense or sense and antisense orientations.

The specification teaches transgenic *Arabidopsis* and tobacco plants transformed with a DNA construct comprising a promoter (35 S CaMV) operably linked to 163 bp of ParG coding sequence of SEQ ID NO: 3 (positions 973 to 1135) in sense orientation and antisense orientation(s) separated by an intron. The transgenic plants exhibited increased tolerance to high light stress. See pages 26-27, example 2; pages 35-37, example 5, tables 1 and 2.

Claim 9 is directed to a DNA molecule comprising any DNA region which when transcribed yields a ParG inhibitory RNA molecule. Claims 10 and 16 are directed to a DNA molecule comprising any DNA region of derived from SEQ ID NO: 3 or a nucleotide sequence encoding SEQ ID NO: 1 and wherein said DNA region is at least

21 to 100 nucleotides in length, and which when transcribed yields a ParG inhibitory RNA molecule.

The specification clearly provides guidance on a DNA molecule comprising a DNA region in sense and antisense orientations separated by a spacer, so that expression of said region from a operably linked promoter results in the formation of a double stranded RNA molecule which would inhibit the expression of an endogenous gene encoding the ParG protein of SEQ ID NO: 1 when said DNA molecule is expressed in a transgenic plant. The breadth of the claims encompass any DNA region (genomic or cDNA), which when transcribed yields ParG inhibitory RNA molecule other than dsRNAi. The specification does not provide guidance on making ParG inhibitory RNA molecules which are not dsRNAi. In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to make a DNA molecule which when transcribed yields any type of ParG inhibitory RNA molecule.

Claims 11-15 are directed to a DNA molecule comprising any DNA region which could be genomic or cDNA, and which when transcribed in a plant yields a ParG inhibitory RNA molecule. Claims 10 and 16 are directed to a DNA molecule comprising any DNA region of derived from SEQ ID NO: 3 or a nucleotide sequence encoding SEQ ID NO: 1 and wherein said DNA region is at least 21 to 100 nucleotides in length, and which when transcribed yields a ParG inhibitory RNA molecule.

The specification clearly provides guidance on a DNA molecule comprising a specific DNA region (coding sequence) in sense and antisense orientations separated

by a spacer, so that expression of said region from a operably linked promoter results in the formation of a double stranded RNA molecule which would interfere or inhibit the expression of endogenous gene encoding a ParG protein of SEQ ID NO: 1. However, the specification does not provide guidance on using noncoding regions or non-specific regions of a DNA encoding ParG, in a method to producing ParG inhibitory molecule. Carthew et al. (Current Opinion in Cell Biology, 13:244-248, 2001) teach that RNAi mediated gene silencing in a transgenic plant requires a DNA construct that comprises cDNA sequences of the target gene to produce a double stranded RNA molecule, which is cleaved to produce siRNAs involved in destroying endogenous target mRNA transcripts. Furthermore, Arziman et al. (Nucleic Acids Research, 33:582-588, 2005) teach that although a dsRNA should be designed to match to one specific gene, off-target effects can occur if siRNAs have sequence homology to genes that are not supposed to be targeted. Furthermore, the knock-down of target transcripts might differ depending on the efficiency of siRNAs derived from long dsRNAs. Besides, it is well established in the art that stability of a double-stranded RNA would depend upon a number of factors, such as sequence composition (for example, GC content), thermodynamic stability etc. It must be emphasized that the breadth of claims encompass inhibiting endogenous ParG gene expression in any plant species which exhibit huge variation in their ParG gene sequences.

In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to use any portion of any gene including at least 21 nucleotides of a sequence encoding SEQ ID NO: 3 to produce gene suppression for

any endogenous ParG gene of any plant species. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

It is noted that instantly instant ParG inhibitory RNA molecule also reads on antisense and/or sense based gene suppression. The instant claims 9-16 are directed to suppression of endogenous ParG expression in a plant using sense or antisense sequence derived from any ParG gene sequence.

Antisense suppression of gene expression is highly unpredictable, and the prior art suggests that success depends on the % identity between the sequence of the antisense construct and the target gene sequence. See Elomaa et al. (Molecular Breeding, 2:41-50, 1996; paragraph bridging pages 47-48, in particular). Further, Colliver et al. (Plant molecular Biology, 35:509-522, 1997) teach that down-regulating the expression of a gene family through antisense method is highly unpredictable. Colliver et al. showed that transformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase resulted in transformants with increased levels of chalcone synthase transcripts due to increased transcription of other members of the gene family (see page 519 left column paragraph 2, in particular). Likewise, Bruening (Proc. Natl. Acad. Sci., 95:13349-133351, 1998) also teach unpredictability of gene-suppression by sense suppression.

It is important to note that the claims encompass any transgenic plant comprising expression of any ParG inhibitory molecule (sense/antisense/dsRNAi) which is either

derived from any ParG gene (claims 11-15), or derived from a nucleotide sequence encoding SEQ ID NO: 1. Keeping in view, huge sequence divergence among the members of ParG family derived from different plant species, undue experimentation would have been required to practice the instantly claimed invention in any plant by expressing said ParG inhibitory molecule to inhibit the endogenous ParG gene expression and/or to obtain stress tolerant transgenic plant.

Claim 16 is directed to any stress tolerant plant. While the specification provides guidance on making high intensity stress tolerant plant of *Arabidopsis* by expressing a ParG inhibitory molecule in the transgenic *Arabidopsis* plant, it does not enable the claim for its full scope. Mittler et al. (Trends in Plant Science, 11:15-19, 2006) teach that tolerance to a combination of different abiotic stresses is likely to be complex trait involving multiple pathways and cross talk between sensors and signal transduction pathways. Reference further teaches that basic differences exist between the acclimated response of plants to different abiotic stress conditions. Furthermore, Logemann et al. (PNAS, 99:2428-2432, 2002) teach that pathogen (biotic stress) overrides UV protection (abiotic stress) by selective transcriptional down-regulation of one or a few metabolic pathways. The reference further teaches that heat shock as well as possibly nutrient depletion overrides both pathogen and UV protection stresses. In the absence of any guidance, undue experimentation would have been required at the time the claimed invention was made to practice the instantly claimed method of producing a plant tolerant to any stress by expressing a ParG inhibitory molecule derived from a nucleotide sequence encoding SEQ ID NO: 1.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Product that is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 11-16 do not mention expressing the DNA construct in the plant cell or plant. See MPEP 2164.08(c).

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

10. Claims 9-16, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a DNA molecule comprising a plant-expressible promoter, a DNA region, which when transcribed yield a ParG inhibitory RNA molecule; and a 3' end region involved in transcription termination and polyadenylation, a plant cell, plant, seed or a method of producing a stress tolerant plant comprising said DNA molecule, or wherein said DNA region comprises a nucleotide sequence in sense or sense and antisense orientations.

The specification describe transgenic *Arabidopsis* and tobacco plants transformed with a DNA construct comprising a promoter (35 S CaMV) operably linked

Art Unit: 1638

to 163 bp of ParG coding sequence of SEQ ID NO: 3 (positions 973 to 1135) in sense orientation and antisense orientation(s) separated by an intron. The transgenic plants exhibited increased tolerance to high light stress. See pages 26-27, example 2; pages 35-37, example 5, tables 1 and 2. It is noted that transgenic plants (expressing the ParG inhibitory molecule derived from SEQ ID NO: 3) exhibiting tolerance to stresses other than high light intensity stress are not disclosed.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*



See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The specification does not have adequate written description for genus of ParG inhibitory molecules under current written description guidelines. Specification does not describe undisclosed structures of Applicant's broadly claimed genus and one skilled in the art cannot reliably predict these structures based upon the disclosure of ParG inhibitory molecule derived from SEQ ID NO: 3 or a nucleotide sequence encoding SEQ ID NO: 1.

Furthermore, said structures of Applicant's broadly claimed genus are not correlated to the function of inhibiting ParG gene expression in a plant transformed with the structures of Applicant's broadly claimed genus. Further, Applicants have failed to describe conserved functional domains that are shared by the undisclosed structures of their broadly claimed genus. Applicants have failed to reduce their broadly claimed genus to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicants were not in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 9, and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorlach et al. (US Patent Publication No. US2002/0040490, Issued April 4, 2002, Applicant's IDS) taken with the evidence of Panda et al. (Developmental Cell, 3:51-61, 2002, Applicant's IDS).

Gorlach et al. disclose a transgenic plant and a method of making a transgenic plant comprising transformation of said plant with a DNA expression cassette comprising a plant-expressible promoter operably linked to a ParG (poly(ADP-ribose) glycohydrolase) nucleotide sequence as defined in SEQ ID NO: 424, and wherein said

nucleotide sequence is in antisense orientation relative to the promoter, and transcribes to yield a ParG molecule which inhibits the expression of endogenous ParG expression of the transformed plant. The reference discloses seeds of the transformed plant and a method of transferring said DNA expression cassette to a non-transgenic plant through crossing between said transgenic plant and the plant lacking said DNA expression cassette. See in particular, SEQ ID NO: 424; claims 9-16, 20, 21; paragraphs 0010; 0102-0111; table 1, page 27.

The property of stress tolerance is inherent to the method comprising expression of the ParG inhibitory molecule within the transgenic plant cell. This is evidenced by Panda et al. who disclose high light stress tolerance property of an *Arabidopsis* plant disrupted in endogenous ParG gene expression.

Accordingly, Gorlach et al. anticipated the claimed invention.

12. Claims 9-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Chang et al. (WIPO, WO 03/000898, Published January 3, 2000, Applicant's IDS).

Chang et al. disclose a transgenic plant and a method of making a transgenic plant comprising transformation of said plant with a DNA expression cassette comprising a plant-expressible promoter operably linked to a ParG (poly(ADP-ribose) glycohydrolase) nucleotide sequence as defined in SEQ ID NO: 550 which is identical in sequence to instant SEQ ID NO: 3, and wherein said nucleotide sequence is in antisense orientation relative to the promoter, and transcribes to yield a ParG molecule which inhibits the expression of endogenous ParG expression of the transformed plant. The reference also discloses down-regulation of endogenous ParG gene expression in

a plant comprising transformation of a DNA construct comprising sense and antisense sequences of SEQ ID NO: 550 which yields a double stranded RNAi (inhibitory molecule) to down-regulate or inhibit endogenous ParG gene expression in said plant. The reference discloses seeds of the transformed plant and a method of transferring said DNA expression cassette to a non-transgenic plant through crossing between said transgenic plant and the plant lacking said DNA expression cassette. See in particular, SEQ ID NO: 550; claims 27-57, 57-58, 63-67; pages 98-99, 100-108.

### ***Conclusions***

13. Claims 9-16, and 20-21 are rejected.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PHUONG T. BUI  
PRIMARY EXAMINER